

106TH CONGRESS  
1ST SESSION

# H.R. 2634

To amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule IV or V for maintenance treatment or detoxification treatment.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 29, 1999

Mr. BLILEY (for himself, Mr. GREEN of Texas, Mr. OXLEY, Mr. BOUCHER, Mr. COX, Mr. GREENWOOD, and Mr. COBLE) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

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## A BILL

To amend the Controlled Substances Act with respect to registration requirements for practitioners who dispense narcotic drugs in schedule IV or V for maintenance treatment or detoxification treatment.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Drug Addiction Treat-  
5 ment Act of 1999”.

1 **SEC. 2. AMENDMENT TO CONTROLLED SUBSTANCES ACT.**

2 (a) IN GENERAL.—Section 303(g) of the Controlled  
3 Substances Act (21 U.S.C. 823(g)) is amended—

4 (1) in paragraph (2), by striking “(A) security”  
5 and inserting “(i) security”, and by striking “(B)  
6 the maintenance” and inserting “(ii) the mainte-  
7 nance”;

8 (2) by redesignating paragraphs (1) through  
9 (3) as subparagraphs (A) through (C), respectively;

10 (3) by inserting “(1)” after “(g)”;

11 (4) by striking “Practitioners who dispense”  
12 and inserting “Except as provided in paragraph (2),  
13 practitioners who dispense”; and

14 (5) by adding at the end the following para-  
15 graph:

16 “(2)(A) Subject to subparagraphs (D) and (I), the  
17 requirements of paragraph (1) are waived in the case of  
18 the dispensing, by a practitioner, of narcotic drugs in  
19 schedule IV or V or combinations of such drugs if the  
20 practitioner meets the conditions specified in subpara-  
21 graph (B) and the narcotic drugs or combinations of such  
22 drugs meet the conditions specified in subparagraph (C).

23 “(B) For purposes of subparagraph (A), the condi-  
24 tions specified in this subparagraph with respect to a prac-  
25 titioner are that, before dispensing narcotic drugs in  
26 schedule IV or V or combinations of such drugs to patients

1 for maintenance or detoxification treatment, the practi-  
2 tioner submit to the Secretary a notification of the intent  
3 of the practitioner to begin dispensing the drugs or com-  
4 binations for such purpose, and that the notification con-  
5 tain the following certifications by the practitioner:

6           “(i) The practitioner is a physician licensed  
7           under State law, and the practitioner has, by train-  
8           ing or experience, the ability to treat and manage  
9           opiate-dependent patients.

10           “(ii) With respect to patients to whom the prac-  
11           titioner will provide such drugs or combinations of  
12           drugs, the practitioner has the capacity to refer the  
13           patients for appropriate counseling and other appro-  
14           priate ancillary services.

15           “(iii) In any case in which the practitioner is  
16           not in a group practice, the total number of such pa-  
17           tients of the practitioner at any one time will not ex-  
18           ceed the applicable number. For purposes of this  
19           clause, the applicable number is 40, except that the  
20           Secretary may by regulation change such total num-  
21           ber.

22           “(iv) In any case in which the practitioner is in  
23           a group practice, the total number of such patients  
24           of the group practice at any one time will not exceed  
25           the applicable number. For purposes of this clause,

1 the applicable number is 40, except that the Sec-  
2 retary may by regulation change such total number,  
3 and the Secretary for such purposes may by regula-  
4 tion establish different categories on the basis of the  
5 number of practitioners in a group practice and es-  
6 tablish for the various categories different numerical  
7 limitations on the number of such patients that the  
8 group practice may have.

9 “(C) For purposes of subparagraph (A), the condi-  
10 tions specified in this subparagraph with respect to nar-  
11 cotic drugs in schedule IV or V or combinations of such  
12 drugs are as follows:

13 “(i) The drugs or combinations of drugs have,  
14 under the Federal Food, Drug, and Cosmetic Act or  
15 section 351 of the Public Health Service Act, been  
16 approved for use in maintenance or detoxification  
17 treatment.

18 “(ii) The drugs or combinations of drugs have  
19 not been the subject of an adverse determination.  
20 For purposes of this clause, an adverse determina-  
21 tion is a determination published in the Federal  
22 Register and made by the Secretary, after consulta-  
23 tion with the Attorney General, that the use of the  
24 drugs or combinations of drugs for maintenance or  
25 detoxification treatment requires additional stand-

1 ards respecting the qualifications of practitioners to  
2 provide such treatment, or requires standards re-  
3 specting the quantities of the drugs that may be pro-  
4 vided for unsupervised use.

5 “(D)(i) A waiver under subparagraph (A) with re-  
6 spect to a practitioner is not in effect unless (in addition  
7 to conditions under subparagraphs (B) and (C)) the fol-  
8 lowing conditions are met:

9 “(I) The notification under subparagraph (B) is  
10 in writing and states the name of the practitioner.

11 “(II) The notification identifies the registration  
12 issued for the practitioner pursuant to subsection  
13 (f).

14 “(III) If the practitioner is a member of a  
15 group practice, the notification states the names of  
16 the other practitioners in the practice and identifies  
17 the registrations issued for the other practitioners  
18 pursuant to subsection (f).

19 “(ii) The Secretary shall provide to the Attorney Gen-  
20 eral such information contained in notifications under sub-  
21 paragraph (B) as the Attorney General may request.

22 “(E)(i) If a practitioner is not registered under para-  
23 graph (1) and, in violation of the conditions specified in  
24 subparagraphs (B) through (D), dispenses narcotic drugs  
25 in schedule IV or V or combinations of such drugs for

1 maintenance treatment or detoxification treatment, the  
2 Attorney General may, for purposes of section 304(a)(4),  
3 consider the practitioner to have committed an act that  
4 renders the registration of the practitioner pursuant to  
5 subsection (f) to be inconsistent with the public interest.

6 “(ii)(I) A practitioner who in good faith submits a  
7 notification under subparagraph (B) and reasonably be-  
8 lieves that the conditions specified in subparagraphs (B)  
9 through (D) have been met shall, in dispensing narcotic  
10 drugs in schedule IV or V or combinations of such drugs  
11 for maintenance treatment or detoxification treatment, be  
12 considered to have a waiver under subparagraph (A) until  
13 notified otherwise by the Secretary.

14 “(II) For purposes of subclause (I), the publication  
15 in the Federal Register of an adverse determination by  
16 the Secretary pursuant to subparagraph (C)(ii) shall (with  
17 respect to the narcotic drug or combination involved) be  
18 considered to be a notification provided by the Secretary  
19 to practitioners, effective upon the expiration of the 30-  
20 day period beginning on the date on which the adverse  
21 determination is so published.

22 “(F)(i) With respect to the dispensing of narcotic  
23 drugs in schedule IV or V or combinations of such drugs  
24 to patients for maintenance or detoxification treatment,  
25 a practitioner may, in his or her discretion, dispense such

1 drugs or combinations for such treatment under a reg-  
2 istration under paragraph (1) or a waiver under subpara-  
3 graph (A) (subject to meeting the applicable conditions).

4 “(ii) This paragraph may not be construed as having  
5 any legal effect on the conditions for obtaining a registra-  
6 tion under paragraph (1), including with respect to the  
7 number of patients who may be served under such a reg-  
8 istration.

9 “(G) For purposes of this paragraph, the term ‘group  
10 practice’ has the meaning given such term in section  
11 1877(h)(4) of the Social Security Act.

12 “(H) During the 3-year period beginning on the date  
13 of the enactment of the Drug Addiction Treatment Act  
14 of 1999, any law or regulation of a State or political sub-  
15 division of a State that is in conflict with this paragraph  
16 is superseded by this paragraph. If before the expiration  
17 of such period a State or political subdivision of a State  
18 enacts such a law, then upon the expiration of the period  
19 this paragraph ceases to supersede the law.

20 “(I)(i) This paragraph takes effect on the date of the  
21 enactment of the Drug Addiction Treatment Act of 1999,  
22 and remains in effect thereafter except as provided in  
23 clause (iii) (relating to a decision by the Secretary or the  
24 Attorney General that this paragraph should not remain  
25 in effect).

1       “(ii) For purposes relating to clause (iii), the Sec-  
2 retary and the Attorney General may, during the 3-year  
3 period beginning on the date of the enactment of the Drug  
4 Addiction Treatment Act of 1999, make determinations  
5 in accordance with the following:

6           “(I) The Secretary may make a determination  
7 of whether treatments provided under waivers under  
8 subparagraph (A) have been effective forms of main-  
9 tenance treatment and detoxification treatment in  
10 clinical settings; may make a determination of  
11 whether such waivers have significantly increased  
12 (relative to the beginning of such period) the avail-  
13 ability of maintenance treatment and detoxification  
14 treatment; and may make a determination of wheth-  
15 er such waivers have adverse consequences for the  
16 public health.

17           “(II) The Attorney General may make a deter-  
18 mination of the extent to which there have been vio-  
19 lations of the numerical limitations established  
20 under subparagraph (B) for the number of individ-  
21 uals to whom a practitioner may provide treatment;  
22 may make a determination of whether waivers under  
23 subparagraph (A) have increased (relative to the be-  
24 ginning of such period) the extent to which narcotic  
25 drugs in schedule IV or V or combinations of such

1 drugs are being dispensed or possessed in violation  
2 of this Act; and may make a determination of  
3 whether such waivers have adverse consequences for  
4 the public health.

5 “(iii) If, before the expiration of the period specified  
6 in clause (ii), the Secretary or the Attorney General pub-  
7 lishes in the Federal Register a decision, made on the  
8 basis of determinations under such clause, that this para-  
9 graph should not remain in effect, this paragraph ceases  
10 to be in effect 60 days after the date on which the decision  
11 is so published. The Secretary shall in making any such  
12 decision consult with the Attorney General, and shall in  
13 publishing the decision in the Federal Register include any  
14 comments received from the Attorney General for inclu-  
15 sion in the publication. The Attorney General shall in  
16 making any such decision consult with the Secretary, and  
17 shall in publishing the decision in the Federal Register  
18 include any comments received from the Secretary for in-  
19 clusion in the publication.”.

20 (b) CONFORMING AMENDMENTS.—Section 304 of the  
21 Controlled Substances Act (21 U.S.C. 824) is amended—

22 (1) in subsection (a), in the matter after and  
23 below paragraph (5), by striking “section 303(g)”  
24 each place such term appears and inserting “section  
25 303(g)(1)”; and

1           (2) in subsection (d), by striking “section  
2           303(g)” and inserting “section 303(g)(1)”.

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